The opinion in support of the decision being entered today was not written for publication and is not precedent of the Board.

Paper No. 29

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte MARIE E. BECKNER, HENRY C. KRUTZSCH
and LANCE A. LIOTTA

_____

Appeal No. 1997-2372
Application 08/083,945

_____

ON BRIEF

_____

Before William F. Smith, Adams, and Mills, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 6, 10, 35, 36, 37, which are pending in this application. We also note that non-elected claims 1-5, 8, 9, 11-18, 21-25, 28 and 31-34 remain pending in the application but are not the subject of this appeal.

According to appellants, claims 6, 10, 35 stand or fall together with respect to the rejection under 35 U.S.C. § 112, first paragraph (Paper No. 24, page 3). Claims 36 and 37 stand alone, with respect to the rejection under 35 U.S.C. § 112, first paragraph (Paper No. 24, page 3). We affirm the rejection of the claims 6, 10, 35 under 35 U.S.C. § 112, first paragraph. The rejection of claims 36 and 37 is reversed.

Thus, we affirm-in-part.

Claims 6, 36 and 37 are illustrative of the claims on appeal and read as follow:

6. A substantially pure polypeptide comprising an amino acid sequence showing at least 90% sequence identity to SEQ ID NO. 7, or a fragment thereof.

36. The substantially pure polypeptide of claim 6, comprising the amino acid sequence of SEQ. ID. No. 7.

37. The substantially pure polypeptide of claim 6 that is capable of binding to heparin.

The document of record relied upon by the examiner in rejecting the appealed claims is:

Hill “Immunoaffinity Purification with Monoclonal Antibodies,” Monoclonal Antibodies, pp. 121-136 (1995).

Appellants rely on Exhibits A-K attached to the Reply Brief.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejection, we make reference to the Examiner's Answer (Paper No. 25, mailed October 30, 1995) and Supplemental Examiner's Answer (Paper No. 28, mailed February 28, 1996) for the examiner's complete reasoning in support of the rejection, and to the appellants' brief (Paper No. 24, filed July 24, 1995) and Reply Brief (Paper No. 26, filed January 2, 1996) for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

Claim Interpretation

Our appellate reviewing court stated in Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1567-1568, 1 USPQ2d 1593, 1597 (Fed. Cir.), cert denied, 481 U.S. 1052 (1987):

> Analysis begins with a key legal question -- what is the invention claimed? Courts are required to view the claimed invention as a whole. 35 U.S.C. 103. Claim interpretation, in light of the specification, claim language, other claims, and

> prosecution history, is a matter of law and will normally control the remainder of the decisional process. [Footnote omitted.]

To that end, we also note that during ex parte prosecution, claims are to be given their broadest reasonable interpretation consistent with the description of the invention in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). The doctrine of claim differentiation creates a presumption that each claim in a patent has a different scope. Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1187, 48 USPQ2d 1001, 1005 (Fed. Cir. 1998). "There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant." Id. at 1005. For purposes of this appeal, we interpret claim 6, directed to "A substantially pure polypeptide comprising an amino acid sequence showing at least 90% sequence identity to SEQ ID NO. 7, or a fragment thereof," as broadly encompassing both peptides which bind to heparin and peptides which do not bind to heparin.[1] This interpretation is supported by the doctrine of claim differentiation, as claim 37, dependent upon claim 6, is directed to "The substantially pure peptide of claim 6, that is capable of binding to heparin." Therefore, we interpret claim 37 as directed to a subset of the

[1] SEQ ID NO:7 is an amino acid sequence corresponding to AAMP-1 polypeptide encoded by an open reading frame in DNA of AAMP-1. Specification pages 15 and 25.

polypeptides of claim 6 which are capable of binding to heparin. We interpret claim 36 as directed to a specific polypeptide which has a specific sequence as set forth in SEQ ID NO: 7, which is also capable of binding to heparin according to the specification pages 25 and 26, and prosecution history, Paper No. 24, page 23.

DECISION ON APPEAL

Rejection 35 U.S.C. § 112, first paragraph

After having properly determined the scope of the claim at issue, we proceed with deliberations addressing the rejection for lack of enablement under 35 U.S.C. § 112, first paragraph. The specification is objected to, and claims 6, 10, 35, 36, 37 are rejected under 35 U.S.C. § 112, first paragraph.

"To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" [Emphasis added.] Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir.1997) (quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Conversely, the first paragraph of Section 112 requires that the scope of protection sought in a claim bear a reasonable correlation to the scope of enablement provided by the specification. An analysis of whether the claims under appeal are supported by an enabling disclosure requires a determination of whether that disclosure contained sufficient information regarding the subject matter of the

appealed claims as to enable one skilled in the pertinent art to make and use the claimed invention.

In order to establish a prima facie case of non-enablement, the examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure. See In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). The threshold step in resolving this issue is to determine whether the examiner has met his burden of proof by advancing acceptable reasoning inconsistent with enablement.

In the present case, it is the examiner's position that the specification does not set forth sufficient guidance and teachings to enable how to make and/or use fragments, variants and alleles of the polypeptide corresponding to SEQ ID NO:7 (AAMP-1 polypeptide) without undue experimentation. Examiner's answer, page 7, lines 21-24. In addition, the examiner argues that the specification does not enable a method of purifying heparin by binding to AAMP-1 without undue experimentation and lacks enablement for recovering heparin from solution which would be implied in a method of purification. Examiner's answer, page 5, lines 13-21. We agree with the examiner up to a point.

Factors to be considered by the examiner in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman, 230 USPO 546, 547 (Bd. Pat. App. & Int. 1986). They include (1) the quantity of

experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). We note that all of the factors need not be reviewed when determining whether a disclosure is enabling. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir.), cert. denied, 112 S. Ct. 1696 (1991)(noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").

The examiner has determined that based on the specification and state of the art it would require undue experimentation to practice the claimed invention within the scope of the pending claims. Considering the Forman factors set forth above individually, it would appear that the nature of the invention described in claim 6, is directed to "A substantially pure polypeptide comprising an amino acid sequence showing at least 90% sequence identity to SEQ. ID. NO. 7, or a fragment thereof," broadly encompassing both peptides which bind to heparin, and peptides which do not bind to heparin.

With regard to the amount of direction or guidance presented in the specification and the presence or absence of working examples, we find the specification describes a heparin binding site at amino acids 7-12 in P189 (a peptide derived from the amino

terminal region of AAMP-1) and its fragment (SEQ ID Nos: 4 and 6). Specification page 26, lines 4-15. The specification Figures 4 and 5 describe AAMP heparin binding and heparin inhibition of cell adhesion to immobilized P189 peptide.[2] These disclosed peptides with heparin binding properties may be useful for heparin purification and removal of heparin from solutions (specification page 13, lines 30-34).

However, the specification does not describe to those of ordinary skill in the art, other peptides within the scope of claim 6, having 90% homology to SEQ ID NO:7 without heparin binding ability or describe how such peptides may be used. It would also appear that the nature of the invention, peptides having a specific functional property, is generally an unpredictable technology.

Thus, it would reasonably appear that it would require undue experimentation on the part of one of ordinary skill in the art to determine how to use the claimed polypeptides, in order to practice the method of the invention within the full scope of claims 6, 10 and 35,

In this regard, the following passage from PPG Indus. Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996) is instructive here.

> In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the

[2] Note, the specification indicates that the terms “AAMP” or “AAMP-1" refer to the same polypeptide. Specification page 8, lines 26-33.

> claim. See, e.g., In re Goodman, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d. 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); In re Vaeck, 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." Atlas Powder Co., v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:
>
> > The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.
>
> Ex parte Jackson, 217 USPQ 804, 807 (1982).

In the case before us having broad claim scope, the examiner has put forth facts which establish a prima facie case of non-enablement, and which provide a reasonable explanation as to why the scope of protection provided by claims 6, 10 and 35 is not adequately enabled by the disclosure.

The examiner also argues that the specification does not enable a method of purifying heparin by binding to AAMP without undue experimentation and lacks

enablement for recovering heparin from solution which would be implied in a method of purification. Examiner's answer, page 5, lines 13-21.

Appellants respond to this argument with rebuttal evidence showing that ionic bonds form between heparin and heparin binding proteins and that such bonds are readily dissociated under mild conditions by raising the salt concentration of the medium. Reply Brief, page 6 and Exhibits A-K. For this reason, appellants submit that one of ordinary skill in the art would not expect to encounter any difficulties in effecting elution if a heparin affinity column were used for purification. Reply Brief, page 6.

In our view, the examiner has failed to present a sufficient factual basis or evidence to rebut the argument and evidence presented by appellants. Therefore, we disagree with the examiner with respect to the examiner's position of lack of enablement of claims 36 and 37, and find these claims to be enabled by the present specification. It would appear that the specification reasonably describes how to make and how to use peptides with binding affinity to heparin (claim 37), and a specific peptide (SEQ ID NO:7) with binding affinity to heparin (Claim 36), in a manner sufficient for those of ordinary skill in the art to practice the claimed invention within the scope of these claims. We agree with appellants that the examiner has failed to establish that the polypeptides of claims 36 and 37 could not be used in affinity purification of heparin.

CONCLUSION

The rejection of claim 6, 10 and 35 under 35 U.S.C. § 112, first paragraph for lack of enablement is affirmed. The rejection of claims 36 and 37 is reversed.

Affirmed-In-Part

William F. Smith Administrative Patent Judge	)
	) BOARD OF PATENT
Donald E. Adams Administrative Patent Judge	) APPEALS AND
	) INTERFERENCES
Demetra J. Mills Administrative Patent Judge	)

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